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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,368	07/09/2003	Thierry Verpoort	069208.0112	1219
23640	7590	03/30/2006	EXAMINER	
BAKER BOTTS, LLP 910 LOUISIANA HOUSTON, TX 77002-4995			MENON, KRISHNAN S	
			ART UNIT	PAPER NUMBER
			1723	
DATE MAILED: 03/30/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/616,368	Applicant(s) VERPOORT ET AL.	
	Examiner Krishnan S. Menon	Art Unit 1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 24,25,27,28 and 36-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24,25,27,28 and 36-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Claims 24,25,27,28, and 36-54 are pending in the RCE of 3/17/06

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24,25,27,28, and 36-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

All the independent claims (24, 42, 51 and 54) recite the limitation "wherein the polyurethane is not radiation/graft polymerized". This is considered new matter because this limitation reads how the polyurethane is not made; and no disclosure could be found in the specification and claims as originally filed in support of this limitation.

Specification page 9, lines 17-21 discloses:

The use of a polymeric or copolymeric cladding or radiation/grafting of a polymer or copolymer in order to prevent the platelets adhering to the non-woven layers of polyurethane is therefore not necessary in the present invention

This paragraph talks about cladding or grafting a polymer or a copolymer on the non-woven layers of polyurethane, but has nothing to do with how the polyurethane itself was made.

For examination, this limitation is considered as "wherein the polyurethane is not further modified by radiation/graft polymerization after the oxygen plasma treatment".

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 24,25,27,28 and 36-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroki et al (US 5,707,520) in view of Katsurada et al (US 5,498,336).

Kuroki teaches a plasma-treated (column 15 lines 50-65; column 11 lines 34-39) polyurethane material for fluid filter (examples 3, 10-13, etc., table 5), wherein the plasma treated polyurethane is more hydrophilic than untreated (plasma treatment is done for making polyurethane hydrophilic). Kuroki teaches selective leuko-depletion, and better than 2-log reduction of leukocytes with no more than 10% removal of platelets from a platelet solution (see table 5). Instant claims differ from the teaching of Kuroki in the recitation of 'non-woven fabric' for the porous polyurethane in claim 26. Katsurada teaches that the structure of the filter material can be of various forms such as fibrous, aggregate, non-woven or woven fabric, etc. (see column 3 lines 5-27). Thus Katsurada teaches the various porous structures of the porous body as equivalent. Kuroki teaches the filter structure required as a porous body with certain porosity and

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pore diameter ranges (see column 5 line 51 – column 6 line 27; column 17 lines 21-35). Kuroki also teaches that non-woven leukocyte removing filters (natural and synthetic) with good efficiency are common in the art in column 1 lines 45-51. Therefore, it would be obvious to one of ordinary skill in the art at the time of invention that the structure of the porous body as taught by Kuroki can be non-woven as taught by Katsurada, as long as it otherwise meets the requirements of the porous body as required by the teaching of Kuroki. They are considered equivalent unless the applicant can show otherwise with evidence.

It may also be noted that the limitation “operable to selectively leukodeplete ...” is functional language, which is not a positive limitation, but only requires the ability to so perform. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board’s finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

With respect to the limitation, wherein the polyurethane is not further modified by radiation/graft polymerization after plasma treatment, Kuroki teaches hydrophilic plasma treatment (column 11 lines 37-39, column 9 lines 20-24) without having any further graft polymerization.

2. Claims 24,25,27,28 and 36-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus et al (US 5,820,755) in view of "Adsorption of blood proteins on glow-discharge-modified polyurethane membranes", Kayirhan, et al, Journal of Appl. Polym. Sci., (81) pp 1322-1332, Aug 2001.

Kraus teaches a leuko-reduction filter comprising polyurethane non-woven layers (column 2 lines 20-30), which gives approximately 2 log reduction of leukocytes (example 5). Pore sizes are 5-15  $\mu\text{m}$  (column 2 lines 20-30). Kraus differs from the claims in the oxygen plasma treatment. Kayirhan teaches plasma treatment, especially oxygen plasma to make polyurethane more hydrophilic and to improve blood-compatibility and reduction of platelet adhesion (see abstract, left column, paragraph 3 of page 1323, conclusion starting on page 1331, and protein adsorption studies on page 1326). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Kayirahn in the teaching of Kraus to have the polyurethane plasma treated to improve its blood compatibility such as reducing platelet adhesion.

Selective leukodepletion containing platelets – the Kraus reference teaches the filter as intended for blood products such as red cell concentrates or platelet concentrates, but provides no data for the platelet concentrates. However, since the

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references teach the same filter as claimed, platelet removal of less than 20 or 15% would be inherent.

### ***Response to Arguments***

Applicant's arguments filed 3/17/06 have been fully considered but they are not persuasive for the 103 rejection.

In response to the argument that the table 5 of Kuroki reference has an error: there is no error in the Kuroki reference, table 5. Kuroki reference teaches the filter system that removes leukocytes, separates platelets from leukocytes, and separates red blood cells – in essence, it does separate leukocytes, platelets and red blood cells into separate groups each with efficiency >90%. Leukocyte remover is described in column 8 line 7 – column 9 line 36; particularly, column 9 lines 19-29 where leukocytes removal from platelet concentrate is taught, which meets the claims since platelets pass through while leukocytes are held by the filter.

Re the argument about the deficiencies in the Katsurada reference: the argument is not commensurate in scope with the rejection. Katsurada is used only to show that the filter can be in the form of non-woven.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Krishnan Menon', with a stylized, cursive script.

Krishnan Menon  
Patent Examiner  
3/24/06